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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,596	05/30/2006	Gal Yadid	1011/20	7721
7590	04/22/2008		EXAMINER	
Mark Friedman Bill Polkinghorn 9003 Florin Way Upper Marlboro, MD 20772			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER
			1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,596	YADID ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 September 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>7/17/06</u> .	6) <input type="checkbox"/> Other: ____ .

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Claims 1-27 are pending.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Diamond et al. (1999) *Hippocampus*, Vol. 9, pp. 542-552.

Diamond teaches rats conditioned to exhibit recurrence of trauma upon repeated exposures to a cat (page 547, figure 1). As is evident from the data presented in figure 1, rats exposed to a cat several days in a row, showed decreasing memory retention in the six-arm maze test, with a confidence of $P < .05$ (page 547, figure 1, legend, lines 1-6). As there are no structural differences between the animals claimed and those of Diamond, the particular phenotypes claimed, Wolframin and Sigma 1 receptor levels or having 2 or 3 PTSD behaviors would be inherent to the rats of Diamond.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or

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unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004),

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

See MPEP 2112, inherency.

Further, Diamond produced the rats by determining the baseline level for 12 rats prior to exposure to a stressor, a cat (page 545, col. 1, parag. 2, lines 1-10). After exposure to the cat, the rats are retested in the six-arm maze (page 545, col. 1, parag. 2, lines 16-19 and page 547, col. 2, parag. 3, lines 1-7). The rats were re-exposed and retested daily of six days (*Ibid.*) Error rates were measured as the mean average of the group of rats tested (page 547, col. 2, parag. 3, lines 1-3). The determinations were made by comparing the rats together (page 547, col. 4, parag. 1). Thus, Diamond clearly anticipates the claimed invention.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Diamond et al. (1999) *Hippocampus*, Vol. 9, pp. 542-552.

Diamond teaches rats conditioned to exhibit recurrence of trauma upon repeated exposures to a cat (page 547, figure 1). As a patentable difference between the rat of Diamond and that of the claim cannot be discerned, the animal claimed is seen as the rat of Diamond produced by a different method. In the alternative, the rat of Diamond renders the claimed animal obvious as any differences would not affect the structure or use of the rat. Thus, Diamond anticipates or makes obvious the claimed invention.

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[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972))."

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

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In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934.) See MPEP 2113 and MPEP 2112.01.

See MPEP 2113, Product-By-Process.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond et al. (1999) Hippocampus, Vol. 9, pp. 542-552 in view of Cohen et al. (2000) Europ. Neuropsychopharmacology, Vol. 10, pp. 429-435.

Diamond teaches a method of producing rats affected by traumatic stress by determining the baseline level for 12 rats prior to exposure to a stressor, a cat (page 545, col. 1, parag. 2, lines 1-10). After exposure to the cat, the rats are retested in the six-arm maze (page 545, col. 1, parag. 2, lines 16-19 and page 547, col. 2, parag. 3, lines 1-7). Error rates were measured as the mean average of the group of rats testes (page 547, col. 2, parag. 3, lines 1-3).

Cohen teaches stress hormones, such as ATCH and corticosterone, alter after experiencing chronic stress, although the results seem to vary (page 433, col. 1, parag. 1, lines 1-10). Cohen also teaches in PTSD patients the conventional thought is cortisol is reduced (page 433, col. 1, parag. 1, lines 11-16). Cohen also teaches rats exposed to cat scent once, produced the generalized anxiety seen in PTSD patients (page 433, col. 1, parag. 2). Therefore Cohen offers teachings, suggestions and motivation to determine plasma levels of ATCH, corticosterone and cortisol in rats exhibiting PTSD behavior.

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At the time of the instant invention, it would have been obvious to the ordinary artisan to produce rats exhibiting a PTSD behavior as taught by Diamond and further determining the effect of traumatic stress on plasma levels of ATCH, corticosterone and cortisol.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." In the present situation, rationales A, B, E and G are applicable. The claimed method was known in the art at the time of filing as indicated by Diamond and Cohen. Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both *Graham* and *KSR*.

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Claims 6, 10 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond et al. (1999) Hippocampus, Vol. 9, pp. 542-552 in view of Adamec et al. (1999) Physiology and Behav., Vol. 65, pp. 723-737.

Diamond produced the rats by determining the baseline level for 12 rats prior to exposure to a stressor, a cat (page 545, col. 1, parag. 2, lines 1-10). After exposure to the cat, the rats are retested in the six-arm maze (page 545, col. 1, parag. 2, lines 16-19 and page 547, col. 2, parag. 3, lines 1-7). Error rates were measured as the mean average of the group of rats tested (page 547, col. 2, parag. 3, lines 1-3).

Adamec teaches determining passive behavior in cat-exposed rats by analyzing videotapes of rat-cat interactions for freezing (page 725, col. 1, parag. 5 and 6).

Therefore it would have been obvious to the ordinary artisan at the time of the instant invention to produce rats as taught by Diamond and analyze them for freezing as taught by Adamec.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a

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different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." In the present situation, rationales A, B, E and G are applicable. The claimed method was known in the art at the time of filing as indicated by Diamond and Adamec. Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both Graham and KSR.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

April 22, 2008